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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,420	08/30/2001	Jason P. Chinn	P-097-R	7837

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THERAVANCE, INC.  
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EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/943,420

Applicant(s)

Chinn et al.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 40-74 ☒ are pending in the application.
- 4a) Of the above, claim(s) 41, 44, 45, 54, 60-62, 64, and 66 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40, 46-53, 55-59, 63, 65, and 70-72 ☒ are rejected.
- 7) ☒ Claim(s) 42, 43, 67-69, 73, and 74 ☒ are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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### **DETAILED ACTION**

Claims 40-74 are pending in this application.

#### ***Election/Restriction***

Applicant's election with traverse of Group I, claims 40-59 and 61-74 drawn to compounds of formula (I), formula (XXIX), or formula (XXX) wherein Y is heterocyclyl having one nitrogen atom as the only ring heteroatom, corresponding composition and method of use in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the restriction requirement is improper. This is not found persuasive because the compounds of instant claims represent two heterocyclic groups attached to each other through two phenyl groups all of which are attached through diverse linking moieties, thereby representing a plurality of compounds all of which are classified separately in various class/subclasses (involving review of thousands of patent documents) and require separate burdensome searches in the literature and computer databases. Compounds containing such diverse groups do not form a single inventive concept within the meaning of 35 U.S.C. 121 because a reference that anticipates or renders obvious one of the groups would not necessarily render obvious another group and applicants have not clearly stated on the record that this is not the case. Applicant's argument that the compounds share a common utility and a substantial structural feature is considered, however, this is not deemed to be persuasive. The only common substantial feature in the claimed nucleus is the presence of two phenyl groups, which in itself is not sufficient to establish as a 'substantial structural feature'.

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The claimed compounds contain plural rings/ring systems attached through diverse linking groups as can be seen from the various structural formulae and the definitions of variables, which is contradictory to the argument of common substantial structure feature.

The instant claims do encompass separate and distinct inventions that have acquired separate status in the art, will support separate patents, and will require different fields of search for the respective inventions. Restriction practice in the case of Markush-type claims is clear from MPEP § 803.02, wherein it is clearly stated that the search and examination of an entire Markush-type claim can be made **when it is not a serious burden** to the examiner. However, in the instant case the instant claims represents multiple genii based on formula (I) (as can be seen from figures 1-3), which further define a plurality of rings/ring systems, linked through diverse linking moieties, which further carrying a complex variety of substituent groups. The resulting compounds are not so closely related, they are classified separately, and would support separate patents. Applicant's arguments referring MPEP § 803.02 and *In re Weber* are fully considered but they were not found to be persuasive for the reasons provided above.

The requirement is still deemed proper and is therefore made FINAL.

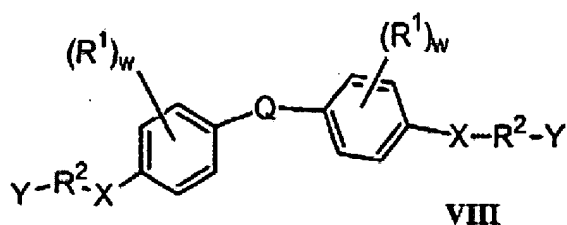
Claim 60 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Applicant's election of the species of compound 1 (Table 1, page 5) is acknowledged. The elected species represents a compound of formula (I) wherein Q is -CH<sub>2</sub>- which is attached

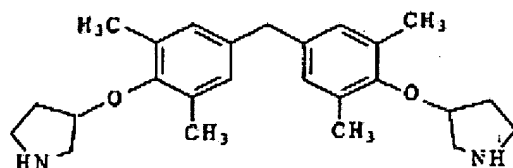
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to the para position of each of the phenyl rings with respect to  $-X-R^2-Y$  (as depicted in Figure 1, formula VIII); X is  $-O-$ ;  $R^2$  is a covalent bond;  $R^1$  is  $CH_3$ ;  $w = 2$ ; and Y is a 3-pyrrolidine.

Claims\* 40, 42, 43, 46-53, 55-58, 63, 67 and 69-74 read on the elected species.



Compound 1:



*\*Note: Applicant indicated that claim 64 also reads on the elected species (see page 4, line 27), however, claim 64 depends from claim 41 and as claim 41 does not read on the elected species and therefore, claim 64 also does not read on the elected species.*

The guidelines in MPEP § 803.02 provide that upon examination if prior art is found for the elected species, the examination will be limited to the elected species.

Content of MPEP § 803.02 is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the

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elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species was not found in the prior art and as per the guidelines above, the search was expanded to cover compounds of **formula VIII** wherein:

Q is -CH<sub>2</sub>-;

X is -O- or -NH-;

R<sup>2</sup> is a covalent bond;

Y is optionally substituted pyrrolidine or piperidine; and

w is 0 or 2,

and art was found. As per the guidelines above, claims 41, 44, 45, 54, 61, 62, 64 and 66 are additionally withdrawn from consideration by the examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

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***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 70 refers to the formulae disclosed in Figures 1-3 without reciting the formulae within the claim. Claim 71 refers to Table 1 in the disclosure for compounds 1-11. Claims should have all limitations within the claim or should refer to other claims for the limitations.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

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Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 40, 46-53, 55-58, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Pastor et al., U.S. Patent Application Publication No. 2002/0007585 (effective filing date May 1, 2000). The instantly claimed compounds read on the compound disclosed in the reference, see the compound of Example 42. (A copy of the corresponding CAPLUS Abstract 135:344384 is provided to show the structural formula of the compound).

2. Claims 40, 46-53, 55-57, 59, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 122:291731. The instantly claimed compounds read on the reference disclosed compound, see compound having RN 163215-26-7 in the enclosed copy of the CAPLUS computer search report.

3. Claims 40, 46-53, 55-57, 59, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 119:271792. The instantly claimed compounds read on the reference disclosed compound, see compound having RN 151519-05-0 in the enclosed copy of the CAPLUS computer search report.

4. Claims 40, 46-53, 55-57, 59, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 105:209781. The instantly claimed compounds read on the reference disclosed compound, see for example, compound having RN 105247-69-6 in the enclosed copy of the CAPLUS computer search report.



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5. Claims 40, 46-53, 55-57, 59, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 112:199166. The instantly claimed compounds read on the reference disclosed compound, see compound having RN 70689-30-4 in the enclosed copy of the CAPLUS computer search report.

6. Claims 40, 46-53, 55-57, 59, 63, 65, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Murayama et al., U.S. Patent No. 3,904,581. The instantly claimed compounds read on the reference disclosed compound, see compound no. 116 in col. 10. (A copy of the corresponding CAPLUS abstract 84:5991 is also enclosed to show the structural formula of the compound).

*Note: A complete meaningful search and examination could not be performed of the entire claimed genus, therefore, the search was limited to a subgenus (as indicated in page 5 above) around the elected species.*

***Allowable Subject Matter***

Claims 42, 43, 67-69, 73 and 74 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten or amended **limiting the scope to the examined subject matter as indicated above.**

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Claim 71 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Receipt is acknowledged of the Information Disclosure Statement filed on May 29, 2002 and a copy is enclosed here with.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

May 18, 2003